

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	:	Tomsia
Appl. No.	:	09/845,597
Filed	:	April 30, 2001
For	:	GLASS/CERAMIC COATINGS FOR IMPLANTS
Examiner	:	Sperty
Group Art Unit:	:	1771

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**PETITION UNDER 37 CFR §1.181(a)(1)**

Ms. Marian Knode  
Director, Technology Center 1700  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Ms. Knode,

Applicants received a Final Office Action, dated September 27, 2006, rejecting all pending claims, 1, 3, 5, 8-12, 20-28, 30 in the patent application ('597) indicated above. Because Applicants' priority claim to 60/201,556 ('566), filed May 1, 2000, has been denied, the Examiner views publications from February 2000 and June 1999 are prior art to the instant invention. The publications and rejections are as follows:

- (1) "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez-Vega et al, published **February 2000**.
- (2) "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez-Vega et al, published **February 2000**
- (3) "A multilayer approach to fabricate bioactive glass coatings on Ti alloys," by Gomez-Vega et al, published **June 1999**.

Claims 1, 3, 5, 8-12 and 20-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by (1).

Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over (2) and further in view of (3).

Applicants respectfully request review of the Examiner's denial of a priority claim to provisional patent application 60/201,556.

Examiner's Denial of Priority Claim

In The Examiner has denied Applicant's claim for priority to Provisional Application 60/201,556. The reasons given are:

1. The specification of the provisional application does not meet the requirements of a "specification" according to 37 CFR 1.77 (b) and (c), which necessitates a certain format and subject matter for a specification. The present collection of previously published articles, including ones not even written by the inventors, does not comply with 37 CFR 1.77 (b) and (c). Therefore, priority to said provisional application is denied."
2. The IDS designates three articles as Prior Art which are also included as part of the "Provisional Application."
3. The provisional application contains a collection of articles which are not seen to provide support for the claimed invention.

Applicants' Arguments as to Priority Claim

Applicants address the Examiner's reasons for denial of priority claim by number below:

Reason 1

A provisional application need not meet the requirements of a "specification" according to 37 CFR 1.77 (b) and (c), as these sections refer to a regular *utility* application. The requirements for a provisional application are given by 37 CFR 1.51 (c), which states:

(c) A complete provisional application filed under § 1.53(c) comprises:

(1) A cover sheet identifying:

- (i) The application as a provisional application,
- (ii) The name or names of the inventor or inventors, (see § 1.41(a)(2)),
- (iii) The residence of each named inventor,
- (iv) The title of the invention,
- (v) The name and registration number of the attorney or agent (if applicable),
- (vi) The docket number used by the person filing the application to identify the application (if applicable),
- (vii) The correspondence address, and
- (viii) The name of the U.S. Government agency and Government contract number (if the invention was made by an agency of the U.S. Government or under a contract with an agency of the U.S. Government);

- (2) A specification as prescribed by the first paragraph of 35 U.S.C. 112, see § 1.71;
- (3) Drawings, when necessary, see §§ 1.81 to 1.85; and
- (4) The prescribed filing fee and application size fee, see § 1.16.

The first paragraph of 35 U.S.C. 112 states:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The Examiner states that some of the articles contained in the '566 were not written by the inventors. I know of no rule that requires inventors to write their own patent applications. Among the articles in the provisional application are two that were written not by but *about* the inventors and their new, novel bioactive glasses.

Applicants respectfully submit that the provisional application, as filed, meets the criteria for a provisional application as stated in 37 CFR 1.51 (c).

#### Reason 2

The articles contained within '566 are listed also in the IDS for the non-provisional application. The Examiner is mistaken when she states that the IDS designates the articles as "Prior Art".

The following is quoted from the MPEP §2129 IV:

Mer listing of a reference in an information disclosure statement is not taken as an admission that the reference is prior art against the claims. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354-55, 66 USPQ2d 1331, 1337-38 (Fed Cir. 2003) (listing of applicant's own prior patent in an IDS does not make it available as prior art absent a statutory basis); see also 37 CFR 1.97(h) ("The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).").

The listing in the IDS of articles included in the provisional application does not constitute a statement by the Applicants that the articles are prior art.

#### Reason 3

The Examiner states that '566 does not provide support for the claimed invention. Applicants respectfully disagree. The pending claims in '597 are listed below with references to '566 which provide support for the claims.

Independent Claim 1 recites a multilayer article comprising a metal substrate and a first layer comprising a glass composition which comprises, 44.2 to 67.7 wt% SiO<sub>2</sub>, 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na<sub>2</sub>O, 2.2 to 6.5 wt% K<sub>2</sub>O and 6.0 wt% P<sub>2</sub>O<sub>5</sub>, wherein the glass composition contains hydroxyapatite particles in an amount of up to 50 wt%. Support for Claim 1 is indicated in the following Table:

Claim 1	Provisional 60/201,556 ('566)
I. A multilayer article comprising,	
a metal substrate,	Page 2, col 2, 4 <sup>th</sup> full ¶
a first layer comprising an inner and outer surface, said first layer comprising a glass composition,	Page 2, col 2, 4 <sup>th</sup> full ¶
said glass composition comprising, 44.2 to 67.7 wt% SiO <sub>2</sub> , 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na <sub>2</sub> O, 2.2 to 6.5 wt% K <sub>2</sub> O and 6.0 wt% P <sub>2</sub> O <sub>5</sub> ,	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I
wherein said glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 8, col 1 lines 8-9 Page 14, Table II

Claim 3 recites the multilayer article of Claim 1 wherein there is a first intermediate layer that has a glass composition as defined in Claim 1 and is located between the substrate and the first layer. Support for Claim 3 is indicated in the following Table:

Claim 3	Provisional 60/201,556 ('566)
3.The multilayer article of claim 1,	
wherein there is a first intermediate layer having an inner and outer surface, and said first intermediate layer is located between the substrate and first layer,	Page 2, col 2, 4 <sup>th</sup> full ¶
said first intermediate layer comprising a glass composition as defined in claim 1.	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, col 2, 4 <sup>th</sup> full ¶ Page 2, Table I

Claim 5 recites the multilayer article of Claim 3, which has a second intermediate layer with a glass composition as defined in Claim 1 and located between the first intermediate layer and the substrate. The hydroxyapatite concentration is highest in the first layer, lowest in the second intermediate layer, and present in the first intermediate layer in an amount that is between the first layer and the second intermediate layer. Support for Claim 5 is indicated in the following Table:

Claim 5	Provisional 60/201,556 (‘566)
5.The multilayer article of claim 3, wherein there is a second intermediate layer located between the first intermediate layer and the substrate,	Page 2, col 2, 4 <sup>th</sup> full ¶
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, col 2, 4 <sup>th</sup> full ¶ Page 2, Table I
wherein the hydroxyapatite concentration is highest in the first layer, lowest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.	

Claim 8 recites the multilayer article of Claim 1 with a substrate that is Ti or Ti6Al4V.  
Support for Claim 8 is indicated in the following Table:

Claim 8	Provisional 60/201,556 (‘566)
8. The multilayer article of claim 1, wherein the substrate is Ti or Ti6Al4V.	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶

Claim 9 recites the multilayer article of Claim 3 with a glass composition in the first layer, which comprises about 54.5 wt% SiO<sub>2</sub>, about 15 wt% CaO, about 8.5 wt% MgO, about 12.0 wt% Na<sub>2</sub>O, about 4.0 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub> and a glass composition in the first intermediate layer, which comprises about 61.1 wt% SiO<sub>2</sub>, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na<sub>2</sub>O, about 2.8 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>, and a substrate that is Ti or Ti6Al4V. Support for Claim 9 is indicated in the following Table:

Claim 9	Provisional 60/201,556 (‘566)
9.The multilayer article of claim 3, wherein the glass composition in the first layer comprises about 54.5 wt% SiO <sub>2</sub> , about 15 wt% CaO, about 8.5 wt% MgO, about 12.0 wt% Na <sub>2</sub> O, about 4.0 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub> ,	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I Page 7, col 2
and the glass composition in the first intermediate layer comprises about 61.1 wt% SiO <sub>2</sub> , about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na <sub>2</sub> O, about 2.8 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub> ,	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I Page 7, col 2
and the substrate is Ti or Ti6Al4V.	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶

Claim 11 recites the multilayer article of Claim 3 with a glass composition in the first layer and in the first intermediate layer, which comprises about 56.5 wt% SiO<sub>2</sub>, about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na<sub>2</sub>O, about 3.0 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>. The hydroxyapatite amount in the first layer is 50 wt%, and the substrate is Ti or Ti<sub>6</sub>Al<sub>4</sub>V. Support for Claim 11 is indicated in the following Table:

Claim 11	Provisional 60/201,556 (‘566)
11. The multilayer article of claim 3,	
wherein the glass composition in the first layer and the first intermediate layer comprise about 56.5 wt% SiO <sub>2</sub> , about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na <sub>2</sub> O, about 3.0 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub>	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, col 2, 4 <sup>th</sup> full ¶ Page 2, Table I
and the hydroxyapatite amount in the first layer is 50 wt%,	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 8, col 1 lines 8-9 Page 14, Table II
and the substrate is Ti or Ti <sub>6</sub> Al <sub>4</sub> V.	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶

Claim 12 recites the multilayer article of Claim 5 with glass compositions in the first layer, the first intermediate layer and the second intermediate layer each comprising about 61.1 wt% SiO<sub>2</sub>, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na<sub>2</sub>O, about 2.8 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>. The hydroxyapatite amount in the first layer comprises 50 wt%, and the substrate is Ti or Ti<sub>6</sub>Al<sub>4</sub>V. Support for Claim 12 is indicated in the following Table:

Claim 12	Provisional 60/201,556 (‘566)
12. The multilayer article of claim 5,	
wherein the glass composition in the first layer, the first intermediate layer and the second intermediate layer each comprise about 61.1 wt% SiO <sub>2</sub> , about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na <sub>2</sub> O, about 2.8 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub>	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, col 2, 4 <sup>th</sup> full ¶ Page 2 Table I
and the hydroxyapatite amount in the first layer comprises 50 wt%	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 8, col 1 lines 8-9 Page 14, Table II
and the substrate is Ti or Ti <sub>6</sub> Al <sub>4</sub> V.	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶

Independent Claim 20 recites multilayer article comprising a substrate that is Ti or Ti6Al4V, a first layer and n intermediate layers disposed between the first layer and the substrate. The first layer and the n intermediate layers each independently comprise a glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite particles in an amount up to 50 wt%. The glass composition comprises about 44.2 to about 67.7 wt% SiO<sub>2</sub>, about 10.1 to about 23.4 wt% CaO, about 5.7 to about 13.3 wt% MgO, about 10.3 to about 23.6 wt% Na<sub>2</sub>O, about 2.2 to about 6.5 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>. Support for Claim 20 is indicated in the following Table:

Independent Claim 20	Provisional 60/201,556 (*566)
20. A multilayer article comprising,	
a metal substrate comprising Ti or Ti6Al4V,	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶
n intermediate layers, where n is an integer,	Page 2, col 2, 4 <sup>th</sup> full ¶
a first layer comprising an inner and outer surface,	
said n intermediate layers disposed between the metal substrate and the first layer,	Page 2, col 2, 4 <sup>th</sup> full ¶
wherein the n intermediate layers and the first layer each independently comprise a glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite particles (HA),	Page 2, col 2, 4 <sup>th</sup> full ¶
said glass composition comprising, about 44.2 to about 67.7 wt% SiO <sub>2</sub> , about 10.1 to about 23.4 wt% CaO, about 5.7 to about 13.3 wt% MgO, about 10.3 to about 23.6 wt% Na <sub>2</sub> O, about 2.2 to about 6.5 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub> ,	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I
and wherein said hydroxyapatite particles being present in the glass/hydroxyapatite admixture in an amount of up to 50 wt%.	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 8, col 1 lines 8-9 Page 14, Table II

Claim 21 recites the multilayer article of Claim 20 with a first layer that has a glass composition with a SiO<sub>2</sub> content between about 53 to about 57 wt%. Support for Claim 21 is indicated in the following Table:

Claim 21	Provisional 60/201,556 (*566)
21. The multilayer article of claim 20, wherein:	
the first layer has a glass composition which has a SiO <sub>2</sub> content between about 53 to about 57 wt%.	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I

Claim 22 recites the multilayer article of Claim 21, wherein  $n=2$ . Support for Claim 22 is indicated in the following Table:

Claim 22	Provisional 60/201,556 (‘566)
22.The multilayer article of claim 21, wherein $n=2$ .	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2

Claim 23 recites the multilayer article of Claim 1, wherein the first layer has a glass composition with a SiO<sub>2</sub> content between about 53 to about 57 wt%.. Support for Claim 23 is indicated in the following Table:

Claim 23	Provisional 60/201,556 (‘566)
23.The multilayer article of claim 1, wherein: the first layer has a glass composition which has a SiO <sub>2</sub> content between about 53 to about 57 wt%.	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I

Claim 24 recites the multilayer article of Claim 23 wherein  $n=2$ . Support for Claim 24 is indicated in the following Table:

Claim 24	Provisional 60/201,556 (‘566)
24.The multilayer article of claim 23, wherein $n=2$ .	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2

Claim 25 recites the multilayer article of Claim 20 wherein the first layer has a glass composition with a SiO<sub>2</sub> content between about 56 to about 67.7 wt%. Support for Claim 25 is indicated in the following Table:

Claim 24	Provisional 60/201,556 (‘566)
25.The multilayer article of claim 20, wherein: the first layer has a glass composition which has a SiO <sub>2</sub> content between about 56 to about 67.7 wt%.	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I

Claim 26 recites the multilayer article of Claim 25 wherein  $n=2$ . Support for Claim 26 is indicated in the following Table:

Claim 26	Provisional 60/201,556 (‘566)
26.The multilayer article of claim 25, wherein $n=2$ .	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2

Claim 27 recites the multilayer article of Claim 1 wherein the first layer has a glass composition with a SiO<sub>2</sub> content between about 56 to about 67.7 wt%. Support for Claim 27 is indicated in the following Table:

Claim 27	Provisional 60/201,556 (‘566)
27. The multilayer article of claim 1, wherein: the first layer has a glass composition which has a SiO <sub>2</sub> content between about 56 to about 67.7 wt%.	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I

Claim 28 recites the multilayer article of Claim 27 wherein n=2. Support for Claim 28 is indicated in the following Table:

Claim 28	Provisional 60/201,556 (‘566)
28. The multilayer article of claim 27, wherein n=2.	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2

Claim 30 recites the multilayer article of Claim 3 wherein there is a second intermediate layer located between the first intermediate layer and the substrate. The first layer, first intermediate layer and second intermediate layer all comprising a glass composition as defined in Claim 1, and the SiO<sub>2</sub> concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer. Support for Claim 30 is indicated in the following Table:

Claim 30	Provisional 60/201,556 (‘566)
30. The multilayer article of claim 3, wherein there is a second intermediate layer located between the first intermediate layer and the substrate, said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1, wherein the SiO <sub>2</sub> concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2  Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I  Page 7, col 1 last ¶ – col 2

**Conclusion**

In view of the foregoing arguments, Applicants respectfully request that the denial of priority to application 60/201,556 be rescinded. Applicants submit that the application 09/845,597 is entitled to claim priority to provisional patent application 60/201,556.

Please charge any fees due, including fees for extensions of time, to Deposit Account No. 120690.

Respectfully submitted,  
The Regents of the University of California  
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Date: December 7, 2006

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